Notice of Violation Pursuant to Requirements of the Resource Conservation and Recovery Act (RCRA)

TO: Facility Name:	art Medical (oter	
Address: 9600	EAST 39th Str	et et	
The state of the s	The state of the s	4057	
EPA ID Number: MOR 60	0524850	Date: Z	14/2009
This notice is provided to call you This notice does not constitute a cand may not be a complete listing	compliance order (Administrative Civil Complaint)	e with state and federal regulations. pursuant to Section 3008 of RCRA
Citation	Part .	Description	of Violation
100000 25-5. 262 (1)	162.11 toda	12 to make a Hazaelous	waste determination:
	(1)	All pharmaceuticals the	at Ace disposed As
	Biol		ments, creams, pills,
	+Ab	lets, Agrosol inhalers, 8+0	
		and a second of	
	(2)		for Tape disposed
	10-1	ine general MACH	
	ctive actions taken a		of this notice. Your response should the necessary corrective actions.
	U. S. Environmen	ntal Protection Agency, Region	VII
	Environmenta	N Services	
	70/ North 5 Kass as Cin	116 11. 1	
	ATTN. Mich		
If you have any questions about t		to discuss your response, you ma	
[AB] =31-7/64		1 111 121	(Compnance Officer) at
This Notice prepared by	45. Matic		Date: 2/4/2009
The undersigned person acknowle	edges that he/she h	as received a copy of this Notice	e and has read same.
	Printed Name:	KEVIN FETTERS	Date: 2/4/2009
	Signature:	Kew Etct	
	Title:	TIPLETOR FACI	LIT / OPERATIONS.
		Page of	512931

Notice of Violation Pursuant to Requirements of the Resource Conservation and Recovery Act (RCRA)

Facility Name: TO: Address: Date: EPA ID Number: This notice is provided to call your attention to the following areas of noncompliance with state and federal regulations. This notice does not constitute a compliance order (Administrative Civil Complaint) pursuant to Section 3008 of RCRA and may not be a complete listing of all violations resulting from the the inspection. Description of Violation You are requested to submit a written response within 14 calendar days of receipt of this notice. Your response should include a description of all corrective actions taken and/or a schedule for completing the necessary corrective actions. The response should be submitted to: U. S. Environmental Protection Agency, Region VII ATTN. If you have any questions about this Notice or wish to discuss your response, you may call me at (Compliance Officer) at This Notice prepared by _ The undersigned person acknowledges that he/she has received a copy of this Notice and has read same. Date: Printed Name: Signature: Title:

Notice of Violation Pursuant to Requirements of the Resource Conservation and Recovery Act (RCRA)

Address:	
EPA ID Number:	Date:
s notice is provided to call y	your attention to the following areas of noncompliance with state and federal regulations. a compliance order (Administrative Civil Complaint) pursuant to Section 3008 of RCRAing of all violations resulting from the the inspection.
Citation	Description of Violation
Regulation Infor	metron (6) Con of the biothazardous waste
	17) How many colls of 3M Steam Indicator (1) tape used and dispard per month or year.
clude a description of all con	rrective actions taken and/or a schedule for completing the necessary corrective actions.
clude a description of all con	rrective actions taken and/or a schedule for completing the necessary corrective actions.
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clude a description of all con	rrective actions taken and/or a schedule for completing the necessary corrective actions. itted to:
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clude a description of all conhe response should be submit f you have any questions about This Notice prepared by	U. S. Environmental Protection Agency, Region VII ATTN
f you have any questions about this Notice prepared by	U. S. Environmental Protection Agency, Region VII ATTN
This Notice prepared by	U. S. Environmental Protection Agency, Region VII ATTN



February 12, 2009

U.S. Environmental Protection Agency, Region VII Environmental Services 901 North 5th Street Kansas City, KS 66101

Attention: Michael J. Martin

Mr. Martin:

Please find below our response to the notice of violation for Centerpoint Medical Center received during your inspection on February 4, 2009. Also attached/enclosed are responses to the "Request for Information" you provided at the survey.

1. 10CSR25-5.262(1) incorporating 40CFR 262.11–Failure to make a hazardous waste determination – All pharmaceuticals that are disposed as biohazardous waste (ointments, creams, pills, tablets, aerosol inhalers, etc.)

The citation references pharmaceutical products that were opened, but not completely used by the patient. Since the product had come into contact with a patient, it is always considered potentially infectious. Therefore, it is treated as bio-hazardous waste and placed in a bio-hazardous waste container. You stated that as long as there was only a residual amount of product in the vial, syringe, tube, inhaler, etc. that this was the appropriate waste stream. However, if there were anything more than a residual amount it would be considered hazardous waste.

You also questioned what happens when a pill packet is opened but the patient refuses the dose or the pill is dropped on the floor. We have also considered these as contaminated and placed them in the bio-hazardous waste container.

Since the potential exists that some of the unused pharmaceutical products may not only be biohazardous, but hazardous. You felt we must make a determination if the product is hazardous, bio-hazardous, or both. Anything that fell into the hazardous category should be segregated and sent through the hazardous waste stream. The citations states that we failed to make a hazardous waste determination and may be placing hazardous wastes into the bio-hazardous waste stream.



To remedy this citation, we are establishing a new policy for the proper disposal of unused pharmaceuticals. The policy will list all hazardous pharmaceuticals used at Centerpoint Medical Center. The list will be posted in the medication rooms throughout the hospital. Any opened or unused portion of the listed hazardous pharmaceutical products will be returned to the main pharmacy in a sealed bag labeled as "hazardous waste pharmaceutical". The bags will be collected in an appropriate container labeled as "hazardous waste pharmaceuticals." The label will be dated with the date the first product is placed into the container. The container will be stored in the satellite hazardous waste collection area in the pharmacy. It will remain there for a maximum of 12 months or until the container is full. The container will then be moved to the hazardous waste accumulation site until it is removed from the facility through the normal hazardous waste stream process. A uniform hazardous waste manifest will be completed as required.

Opened and unused pharmaceuticals <u>not</u> listed as hazardous will continue to be placed in the bio-hazardous waste container and sent through the biohazardous waste stream.

On February 12, 2009, you contacted me by phone and notified me of a second citation as follows:

2. 40CFR252.20(a)(1) – Hazardous waste disposed of through the general waste stream. 3-M Steam Indicator Tape containing <2% lead carbonate hydroxide CAS 1319-46-6 was disposed of through the general waste stream.

Our Supply Chain Department located a substitute product that does not contain lead or other hazardous material. The 3-M steam sterilizer indicator tape currently in stock will be returned to the manufacturer. Any used product or opened packages will be properly stored, transported, and disposed of as hazardous waste D008 Lead. A uniform hazardous waste manifest will be completed as required.

I trust you will find our response satisfactory. However, should you have any questions please feel free to contact me.

Sincerely, Herrin E. Fietlers

Kevin E. Fetters,

Director of Facility Operations, Centerpoint Medical Center

phone: 816-698-7092 fax: 816-698-7091

email: kevin.fetters@hcamidwest.com

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Responses to Request for Information Items

- 1. Copy of contract with EXP. (enclosed)
- 2. Explain the differences between the nine report categories:
 - a. <u>Hazardous Waste Report</u>: A listing of pharmaceuticals unable to be returned to the manufacturer, determined to be hazardous material, and sent out as hazardous waste by the reverse distributor.
 - b. <u>Processed Indate Report</u>: A listing of products picked up prior to their expiration date, which have now expired and been returned to the manufacturer/vendor.
 - c. <u>Non-scheduled Drug Waste Report</u>: A listing of non-hazardous, non-controlled substances (i.e. non-narcotics) that could not be returned and were shipped out as waste
 - d. <u>Indate Storage Report</u>: A listing of products picked up before their expiration date. They are stored at EXP until their expiration date passes, and then returned to the manufacturer/vendor for credit. At the time they are processed they are placed on the "Processed Indate Report" (see item b above)
 - e. <u>Scheduled Drug Waste Report</u>: A listing of non-hazardous controlled substances (narcotics) that were shipped out as waste
 - f. <u>Returned Drug Summary</u>: A listing of all drugs that were returned to the manufacturer/vendor
 - g. <u>Processed Recall Report Returned</u>: A listing of drugs that were part of a recall notification.
 - h. <u>Returned Non-scheduled Drug Report</u>: A listing of non-controlled substances (non-narcotics) that were returned to the manufacturer or vendor
 - i. <u>Returned Scheduled Drug Report</u>: A listing of controlled substances (narcotics) that were returned to the manufacturer or vendor.
- 3. Describe and explain the EXP inventory activity on-site:
 - EXP is our reverse distributor for outdated and unused pharmaceuticals. They create an itemized inventory of the pharmaceutical products they remove from our site. This is done approximately every 90 days. They transport the product to their place of business and begin the process of returning them to the manufacturer/vendor for credit. The hospital receives a credit from EXP for returned products. It should be noted everything EXP picks up is as product, not waste. Once they have removed the product, they own it and give us credit for the value. They make the determination if the products are hazardous, non-hazardous, controlled substances, non-controlled substances etc. and dispose of them through the appropriate waste stream. EXP provides the hospital itemized reports of the final disposition of all products they removed. (see item 2 above)

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Responses to Request for Information Items

4. Describe and explain the EXP inventory activity back at EXP:
Please direct this question to Todd Barnes, Director of Regional Operations at EXP 913-837-4949.

5. List the generation rates of pharmaceuticals generated on-site and disposed of with the bio-hazardous waste:

Unknown, although we believe it to be an extremely small amount. The hospital provides pharmaceuticals in single dose units. Any unused and unopened pharmaceuticals are returned to the pharmacy for restocking. The only unused or opened pharmaceuticals that could go into the biohazardous waste stream are partially used tubes of ointments, inhalers, or on rare occasions, when a single dose is refused or dropped and contaminated. These products are exposed to the patient or the patient's environment. In as much, they are potentially infectious and placed in a biohazard waste container. They do not go out through the general non-regulated waste stream.

6. Copy of the biohazardous waste disposal contract (enclosed)

7. How many rolls of 3M steam indicator (D008) tape used and disposed of per month?

We use an average of 20 rolls of 3M steam indicator tape per month. The tape is <2% lead carbonate hydroxide and is being replaced with a lead free product.